STATEMENT OF ROBERT SUSSMAN ON EPA's PROPOSED RULE ON TRANSPARENCY IN REGULATORY SCIENCE -- July 17, 2018

My name is Bob Sussman. I'm a former EPA official in the Clinton and Obama Administrations and am now a consultant and attorney. I'm here today representing Safer Chemicals Healthy Families, which leads a coalition of 450 organizations and businesses united by a common concern about toxic chemicals in our homes, places of work, and products we use every day.

I believe that EPA proposal we are discussing today is flawed and misconceived. In the name of "transparency," it will burden EPA scientists with unnecessary and costly procedures that run counter to the Agency's long-standing obligation to base public health decisions on the best available science.

The unspoken premise of the proposal is that unless EPA can guarantee full public access to a study's underlying data, the study must be deemed unreliable and should play no role in assessing a pollutant or chemical's effects on human health. This premise ignores the many ways in which the scientific community, regulators, and the public have traditionally determined the quality and relevance of study results.

Study reports typically explain the protocols used to gather data, the methods used for data analysis, the doses or exposure concentrations at which effects were and were not observed, the nature, severity, and incidence of such effects, and any unusual occurrences that may affect interpretation of the results. This information plays an important role in the peer review process, informing the judgment of independent reviewers as to whether a study is worthy of publication in the scientific literature. Agency reviewers likewise consider these indicators of reliability in deciding how much weight a study deserves in making judgments about hazard and risk. In its narrow focus on a single criterion for study acceptability, the proposal departs from this comprehensive, multi-faceted approach for determining the "best available science" to inform decision-making.

In principle, no one disputes the benefits of improving access to underlying data for research on chemicals and pollutants. The goals of "open science" have received support from several organizations and leading scientific journals and

research institutions have adopted practices and policies to maximize data access. These voluntary efforts, however, do not justify the unprecedented step of requiring EPA to guarantee access to the underlying data for every study it may use for decision-making and to forfeit the ability to consider a study if this requirement has not been met.

EPA scientists working on risk and hazard assessments collect and review thousands of studies. Published reports of these studies typically do not include all underlying data. In such cases, EPA would need to contact the researcher, ascertain the nature and extent of underlying data, and put in place a mechanism for the public to access the data. Analyzing House legislation that would impose similar obligations on EPA, the Congressional Budget Office and EPA staff concluded that the costs of implementation would be at least $250 million a year. Moreover, rather than devoting time and effort to assuring access to underlying data, EPA staff may follow the path of least resistance and simply drop many studies from consideration, shrinking the body of scientific evidence on which decisions are based.

Even with diligent effort by EPA, there are many reasons why disclosure of data sufficient to replicate a study may be impossible. For epidemiology and other studies of human cohorts, privacy protections will often block release of individual medical records. Industry-conducted studies may contain confidential business information (CBI) required to be withheld by law. For studies based on human exposure measurements, replication may be impossible because exposure conditions have changed. Studies attempting to capture the impacts of one-time events like spills or plant explosions will also be inherently unreproducible. And for older studies predating digital technology, retrieving full study records may be difficult or impossible.

The EPA proposal duly notes these obstacles to study replication and provides that exemptions may be granted on a case-by-case basis where "compliance is impracticable." But an exemption process will add to the considerable cost and effort required to implement the proposed rule and may result in disputes and even litigation over whether exemptions are justified.

Is the damage it will inflict on the quality and timeliness of EPA science justified by the benefits of the proposed rule? EPA leaders have painted a bleak picture of

EPA reliance on "secret science" developed behind "closed doors" "based on data that has been withheld from the American people." But is this the reality?

EPA science assessments generally include an exhaustive and critical review of relevant studies and a full explanation of how they are being interpreted. Extensive information about each study is typically part of the public record, even if all underlying data may not be included. EPA assessments are normally subject to public comment and independent peer review. And members of the regulatory community are free at any time to replicate studies they deem flawed or to independently seek access to underlying data and reanalyze them. In short, the "problem" that the proposed rule seeks to fix is largely imaginary.

In conclusion, the Agency's leadership needs to fundamentally rethink this proposed rule. The stakes for EPA science and the protection of public health are simply too high to finalize this deeply problematic and unnecessary proposal.